

## General

### Guideline Title

Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication.

### Bibliographic Source(s)

Society for Vascular Surgery Lower Extremity Guidelines Writing Group, Conte MS, Pomposelli FB, Clair DG, Geraghty PJ, McKinsey JF, Mills JL, Moneta GL, Murad MH, Powell RJ, Reed AB, Schanzer A, Sidawy AN. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication. J Vasc Surg. 2015 Mar;61(3 Suppl):2S-41S. [275 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria

## Recommendations

### Major Recommendations

Definitions of the strength of the recommendations (Grade 1 or 2) and quality of the evidence (Level A–C) are provided at the end of the "Major Recommendations" field.

#### Diagnosis

Recommendations: Diagnosis of Peripheral Arterial Disease (PAD)

1. The Committee recommends using the ankle-brachial index (ABI) as the first-line noninvasive test to establish a diagnosis of PAD in individuals with symptoms or signs suggestive of disease. When the ABI is borderline or normal ( $>0.9$ ) and symptoms of claudication are suggestive, The Committee recommends an exercise ABI. (Grade - 1; Level of Evidence - A)
2. The Committee suggests against routine screening for lower extremity PAD in the absence of risk factors, history, signs, or symptoms of PAD. (Grade - 2; Level of Evidence - C)
3. For asymptomatic individuals who are at elevated risk, such as those aged  $>70$ , smokers, diabetic patients, those with an abnormal pulse examination, or other established cardiovascular disease, screening for lower extremity PAD is reasonable if used to improve risk stratification, preventive care, and medical management. (Grade - 2; Level of Evidence - C)
4. In symptomatic patients who are being considered for revascularization, the Committee suggests using physiologic noninvasive studies, such as segmental pressures and pulse volume recordings, to aid in the quantification of arterial insufficiency and help localize the level of obstruction. (Grade - 2; Level of Evidence - C)

5. In symptomatic patients in whom revascularization treatment is being considered, the Committee recommends anatomic imaging studies, such as arterial duplex ultrasound, computed tomography angiography (CTA), magnetic resonance angiography (MRA), and contrast arteriography. (Grade - 1; Level of Evidence - B)

#### Management of Asymptomatic Patients with PAD

##### Recommendations: Management of Asymptomatic Disease

1. The Committee recommends multidisciplinary comprehensive smoking cessation interventions for patients with asymptomatic PAD who use tobacco (repeatedly until tobacco use has stopped). (Grade - 1; Level of Evidence - A)
2. The Committee recommends providing education about the signs and symptoms of PAD progression to asymptomatic patients with PAD. (Grade - 1; Level of Evidence - Ungraded)
3. The Committee recommends against invasive treatments for PAD in the absence of symptoms, regardless of hemodynamic measures or imaging findings demonstrating PAD. (Grade - 1; Level of Evidence - B)

#### Noninterventional Management of the Patient with IC

##### Recommendations: Medical Treatment for Intermittent Claudication (IC)

1. The Committee recommends multidisciplinary comprehensive smoking cessation interventions for patients with IC (repeatedly until tobacco use has stopped). (Grade - 1; Level of Evidence - A)
2. The Committee recommends statin therapy in patients with symptomatic PAD. (Grade - 1; Level of Evidence - A)
3. The Committee recommends optimizing diabetes control (hemoglobin A<sub>1c</sub> goal of <7.0%) in patients with IC if this goal can be achieved without hypoglycemia. (Grade - 1; Level of Evidence - B)
4. The Committee recommends the use of indicated  $\beta$ -blockers (e.g., for hypertension, cardiac indications) in patients with IC. There is no evidence supporting concerns about worsening claudication symptoms. (Grade - 1; Level of Evidence - B)
5. In patients with IC due to atherosclerosis, the Committee recommends antiplatelet therapy with aspirin (75-325 mg daily). (Grade - 1; Level of Evidence - A)
6. The Committee recommends clopidogrel in doses of 75 mg daily as an effective alternative to aspirin for antiplatelet therapy in patients with IC. (Grade - 1; Level of Evidence - B)
7. In patients with IC due to atherosclerosis, the Committee suggests against using warfarin for the sole indication of reducing the risk of adverse cardiovascular events or vascular occlusions. (Grade - 1; Level of Evidence - C)
8. The Committee suggests against using folic acid and vitamin B<sub>12</sub> supplements as a treatment of IC. (Grade - 2; Level of Evidence - C)
9. In patients with IC who do not have congestive heart failure, the Committee suggests a 3-month trial of cilostazol (100 mg twice daily) to improve pain-free walking. (Grade - 2; Level of Evidence - A)
10. In patients with IC who cannot tolerate or have contraindications for cilostazol, the Committee suggests a trial of pentoxifylline (400 mg thrice daily) to improve pain-free walking. (Grade - 2; Level of Evidence - B)

##### Recommendations: Exercise Therapy

11. The Committee recommends as first-line therapy a supervised exercise program consisting of walking a minimum of three times per week (30-60 min/session) for at least 12 weeks to all suitable patients with IC. (Grade - 1; Level of Evidence - A)
12. The Committee recommends home-based exercise, with a goal of at least 30 minutes of walking three to five times per week when a supervised exercise program is unavailable or for long-term benefit after a supervised exercise program is completed. (Grade - 1; Level of Evidence - B)
13. In patients who have undergone revascularization therapy for IC, the Committee recommends exercise (either supervised or home based) for adjunctive functional benefits. (Grade - 1; Level of Evidence - B)
14. The Committee recommends that patients with IC be followed up annually to assess compliance with lifestyle measures (smoking cessation, exercise) and medical therapies as well as to determine if there is evidence of progression in symptoms or signs of PAD. Yearly ABI testing may be of value to provide objective evidence of disease progression. (Grade - 1; Level of Evidence - C)

#### The Role of Revascularization for IC

##### Recommendations: General Considerations on Invasive Treatment for IC

1. The Committee recommends endovascular therapy (EVT) or surgical treatment of IC for patients with significant functional or lifestyle-limiting disability when there is a reasonable likelihood of symptomatic improvement with treatment, when pharmacologic or exercise therapy, or both, have failed, and when the benefits of treatment outweigh the potential risks. (Grade - 1; Level of Evidence - B)

2. The Committee recommends an individualized approach to select an invasive treatment for IC. The modality offered should provide a reasonable likelihood of sustained benefit to the patient (>50% likelihood of clinical efficacy for at least 2 years). For revascularization, anatomic patency (freedom from hemodynamically significant restenosis) is considered a prerequisite for sustained efficacy. (Grade - 1; Level of Evidence - C)

#### Recommendations: Interventions for Aortoiliac Occlusive Disease (AIOD) in IC

3. The Committee recommends endovascular procedures over open surgery for focal AIOD causing IC. (Grade - 1; Level of Evidence - B)
4. The Committee recommends endovascular interventions as first-line revascularization therapy for most patients with common iliac artery or external iliac artery occlusive disease causing IC. (Grade - 1; Level of Evidence - B)
5. The Committee recommends the selective use of bare-metal stent (BMS) or covered stents for aortoiliac angioplasty for common iliac artery or external iliac artery occlusive disease, or both, due to improved technical success and patency. (Grade - 1; Level of Evidence - B)
6. The Committee recommends the use of covered stents for treatment of AIOD in the presence of severe calcification or aneurysmal changes where the risk of rupture may be increased after unprotected dilation. (Grade - 1; Level of Evidence - C)
7. For patients with diffuse AIOD (e.g., extensive aortic disease, disease involving both common and external iliac arteries) undergoing revascularization, the Committee suggests either endovascular or surgical intervention as first-line approaches. Endovascular interventions that may impair the potential for subsequent AFB in surgical candidates should be avoided. (Grade - 2; Level of Evidence - B)
8. EVT of AIOD in the presence of aneurysmal disease should be undertaken cautiously. The Committee recommends that the modality used should either achieve concomitant aneurysm exclusion or should not jeopardize the conduct of any future open or endovascular aneurysm repair. (Grade - 1; Level of Evidence - C)
9. In all patients undergoing revascularization for AIOD, the Committee recommends assessing the common femoral artery (CFA). If hemodynamically significant CFA disease is present, the Committee recommends surgical therapy (endarterectomy) as first-line treatment. (Grade - 1; Level of Evidence - B)
10. In patients with iliac artery disease and involvement of the CFA, the Committee recommends hybrid procedures combining femoral endarterectomy with iliac inflow correction. (Grade - 1; Level of Evidence - B)
11. The Committee recommends direct surgical reconstruction (bypass, endarterectomy) in patients with reasonable surgical risk and diffuse AIOD not amenable to an endovascular approach, after one or more failed attempts at EVT, or in patients with combined occlusive and aneurysmal disease. (Grade - 1; Level of Evidence - B)
12. In younger patients (age <50 years) with IC, the Committee recommends a shared decision-making approach to engage patients and inform them of the possibility of inferior outcomes with either endovascular or surgical interventions. (Grade - 2; Level of Evidence - C)
13. The Committee recommends either axial imaging (e.g., computed tomography [CT], magnetic resonance [MR]) or catheter-based angiography for evaluation and planning of surgical revascularization for AIOD. (Grade - 1; Level of Evidence - Ungraded)
14. When performing surgical bypass for aortoiliac disease, concomitant aneurysmal disease of the aorta or iliac arteries should be treated as appropriate (exclusion) and is a contraindication to end-to-side proximal anastomoses. (Grade - 1; Level of Evidence - Ungraded)
15. For any bypass graft originating from the CFA, the donor iliac artery must be free of hemodynamically significant disease or any pre-existing disease should be corrected before performing the bypass graft. (Grade - 1; Level of Evidence - Ungraded)

#### Recommendations: Intervention for Femoropopliteal Occlusive Disease (FPOD) in IC

16. The Committee recommends endovascular procedures over open surgery for focal occlusive disease of the superficial femoral artery (SFA) not involving the origin at the femoral bifurcation. (Grade - 1; Level of Evidence - C)
17. For focal lesions (<5 cm) in the SFA that have unsatisfactory technical results with balloon angioplasty, the Committee suggests selective stenting. (Grade - 2; Level of Evidence - C)
18. For intermediate-length lesions (5-15 cm) in the SFA, the Committee recommends the adjunctive use of self-expanding nitinol stents (with or without paclitaxel) to improve the midterm patency of angioplasty. (Grade - 1; Level of Evidence - B)
19. The Committee suggests the use of preoperative ultrasound vein mapping to establish the availability and quality of autogenous vein conduit in patients being considered for infrainguinal bypass for the treatment of IC. (Grade - 2; Level of Evidence - C)
20. The Committee recommends against EVT of isolated infrapopliteal disease for IC because this treatment is of unproven benefit and possibly harmful. (Grade - 1; Level of Evidence - C)
21. The Committee recommends surgical bypass as an initial revascularization strategy for patients with diffuse femoropopliteal (FP) disease, small caliber (<5 mm), or extensive calcification of the SFA, if they have favorable anatomy for bypass (popliteal artery target, good runoff) and have average or low operative risk. (Grade - 1; Level of Evidence - B)
22. The Committee recommends using the saphenous vein as the preferred conduit for infrainguinal bypass grafts. (Grade - 1; Level of Evidence - A)
23. In the absence of suitable vein, the Committee suggests using prosthetic conduit for FP bypass in claudicant patients, if the above-knee

popliteal artery is the target vessel and good runoff is present. (Grade - 2; Level of Evidence - C)

#### Recommendations: Postinterventional Medical Therapy in IC

24. In all patients after endovascular or open surgical intervention for claudication, the Committee recommends optimal medical therapy (antiplatelets agents, statins, antihypertensives, control of glycemia, smoking cessation). (Grade - 1; Level of Evidence - A)
25. In patients undergoing lower extremity bypass (venous or prosthetic), the Committee suggests treatment with antiplatelet therapy (aspirin, clopidogrel, or aspirin plus clopidogrel). (Grade - 2; Level of Evidence - B)
26. In patients undergoing infrainguinal endovascular intervention for claudication, the Committee suggests treatment with aspirin and clopidogrel for at least 30 days. (Grade - 2; Level of Evidence - B)

#### Surveillance After Revascularization for IC

#### Recommendations: Surveillance After Interventions for IC

1. The Committee suggests that patients treated with open or endovascular interventions for IC be monitored with a clinical surveillance program that consists of an interval history to detect new symptoms, ensure compliance with medical therapies, record subjective functional improvements, pulse examination, and measurement of resting and, if possible, postexercise ABIs. (Grade - 2; Level of Evidence - C)
2. The Committee suggests that patients treated with lower extremity vein grafts for IC be monitored with a surveillance program that consists of clinical follow-up and duplex scanning. (Grade - 2; Level of Evidence - C)
3. The Committee suggests that patients who have previously undergone vein bypass surgery for IC and have developed a significant graft stenosis on duplex ultrasound (DUS) be considered for prophylactic reintervention (open or endovascular) to promote long-term bypass graft patency. (Grade - 1; Level of Evidence - C)

#### Definitions

#### Grading of Recommendations Assessment, Development and Evaluation (GRADE) Recommendations Based on Level of Evidence

Grade	Description of Recommendation	Benefit vs. Risk	Methodologic Quality of Supporting Evidence	Implications
1A	Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Randomized controlled trials (RCTs) without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B	Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C	Strong recommendation, low-quality or very-low-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A	Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2B	Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burdens	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2C	Weak recommendation, low-quality or very-low-quality evidence	Uncertainty in the estimates of benefits and risk, and burdens; Risk, benefit, and burdens may be closely balanced	Observational studies or case series	Very weak recommendations; Other alternatives may be reasonable

## Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

Peripheral arterial disease (PAD)

- Asymptomatic disease
- Intermittent claudication (IC)

### Guideline Category

Diagnosis

Evaluation

Management

### Clinical Specialty

Cardiology

Internal Medicine

Surgery

### Intended Users

Physicians

### Guideline Objective(s)

To provide recommendations for evaluation and management of asymptomatic peripheral arterial disease (PAD) and intermittent claudication (IC)

### Target Population

Patients with peripheral arterial disease (PAD) representing a broad spectrum of disease, including asymptomatic through severe limb ischemia

### Interventions and Practices Considered

1. Ankle-brachial index (ABI) to establish diagnosis
2. Screening for lower extremity peripheral arterial disease (PAD)
3. Physiologic noninvasive studies (e.g., segmental pressures, pulse volume recordings) as indicated
4. Anatomic imaging studies (e.g., arterial duplex ultrasound, computed tomography angiography [CTA], magnetic resonance angiography [MRA])

5. Smoking cessation
6. Patient education
7. Statin therapy in patients with symptomatic PAD
8. Diabetes control
9.  $\beta$ -blockers if indicated
10. Antiplatelet therapy
  - Aspirin
  - Clopidogrel
11. Three month trial of cilostazol or pentoxifylline
12. Exercise
  - Supervised exercise program
  - Home-based exercise
13. Assessment of compliance with lifestyle measures and medical therapies
14. Endovascular therapy (EVT)
15. Surgical treatment
16. Covered stents
17. Hybrid procedures combining femoral endarterectomy with iliac inflow correction
18. Axial imaging or catheter-based angiography
19. Surgical bypass
20. Prophylactic reintervention

Note: The following were considered but not recommended: warfarin, folic acid and vitamin B<sub>12</sub>

## Major Outcomes Considered

- Yield of screening
- Benefits and harms of screening
- Death
- Amputation
- Development of symptoms
- Quality of life

## Methodology

### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): Two systematic reviews were prepared to support the development of this guideline (see the "Availability of Companion Documents" field).

#### A Systematic Review for the Screening for Peripheral Arterial Disease in Asymptomatic Patients

##### Study Eligibility and Data Sources

Studies were eligible for this review if they reported on a screening program for peripheral arterial disease (PAD) in asymptomatic individuals using ankle-brachial index (ABI). Studies were included regardless of design (i.e., randomized or not), language, size, or length of follow-up.

The authors updated an evidence report from the U.S. Preventive Services Task Force (USPSTF) published in 2005 that served as a data source up to that date. A comprehensive search of several databases from 2005 to March 2010 was conducted and then updated in June 2014. The databases included Ovid Medline In-Process & Other Non-Indexed Citations, Ovid MEDLINE, Ovid EMBASE, Ovid Cochrane Database of

Systematic Reviews, Ovid Cochrane Central Register of Controlled Trials (CENTRAL), Scopus, and the NGC. The search strategy was designed and conducted by an expert reference librarian with input from the study's principal investigator. Controlled vocabulary supplemented with keywords was used to define the two concept areas, peripheral vascular disease and screening, as well as to limit the search to clinical studies. The detailed strategy is available in the appendix of the systematic review. The authors also included relevant systematic reviews and meta-analyses. For each comparison of interest, evidence was derived from a credible systematic review if it existed; if not, individual studies were evaluated.

#### A Systematic Review of Treatment of Intermittent Claudication in the Lower Extremities

##### Study Eligibility

This systematic review was conducted following recommendations from the Cochrane Collaboration and was reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.

Studies were eligible for this review if they were (1) randomized trials or systematic reviews; (2) enrolled patients with claudication (i.e., symptomatic patients with peripheral vascular disease who had exertional pain with walking); (3) evaluated open bypass, endovascular revascularization, or exercise therapy; and (4) measured the outcomes of interest. Trials exclusively enrolling patients with critical limb ischemia (CLI), defined as rest pain or tissue loss, were excluded.

Exploratory search revealed six existing well-conducted published systematic reviews that searched multiple electronic bibliographic databases between 2005 and 2011. The authors updated these search strategies through June 2014. The details of the search strategies are in the appendix of the systematic review.

## Number of Source Documents

#### A Systematic Review for the Screening for Peripheral Arterial Disease in Asymptomatic Patients

Literature search yielded 446 references, from which 406 were excluded (287 were not original and 119 did not report on screening in asymptomatic patients). Of note, some included studies enrolled a proportion of symptomatic patients with claudication; however, studies that did not enroll any asymptomatic patients were excluded. There were 40 eligible studies enrolling 139,830 screened individuals. Of these 40 studies, 38 reported data on screening yield, 19 reported data on the association between peripheral arterial disease (PAD) and mortality, and 5 reported on outcomes of interventions provided to PAD patients identified through screening. The authors also included two systematic reviews and one individual-patient data meta-analysis.

The authors found no randomized controlled trials that evaluated a PAD screening program in terms of its effect on patient-important outcomes.

#### A Systematic Review of Treatment of Intermittent Claudication in the Lower Extremities

The original search in 2011 identified 853 references and the update in 2014 identified 207 additional ones. The authors excluded 1041 citations for being duplicates of included studies, having no original data, or having an irrelevant population (majority of patients with critical limb ischemia [CLI]).

After screening abstracts and full-text references, the authors finally included 8 systematic reviews (3 Cochrane systematic reviews of randomized trials on exercise therapy, 2 systematic reviews that compared supervised exercise with endovascular therapy, and 3 systematic reviews of nonrandomized surgical case series) and 12 trials evaluating endovascular or open surgical approaches.

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

### Rating Scheme for the Strength of the Evidence

See the "Rating Scheme for the Strength of the Recommendations" field.

## Methods Used to Analyze the Evidence

## Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): Two systematic reviews were prepared to support the development of this guideline (see the "Availability of Companion Documents" field).

### A Systematic Review for the Screening for Peripheral Arterial Disease in Asymptomatic Patients

#### Data Extraction and Analysis

The analytic framework for this review was derived from the essential prerequisites for a screening test and incorporated the approach of the U.S. Preventive Services Task Force (USPSTF) guideline. Therefore, the authors asked five questions and reported the results accordingly (see Figure 1 in the systematic review).

Teams of reviewers, working in duplicates, reviewed the abstracts and full-text articles and extracted descriptive, methodologic quality, and outcome data. The authors used dedicated software (DistillerSR, Ottawa, Canada) to conduct the online article review and data extraction procedures, the latter using piloted electronic forms. Chance-adjusted inter-reviewer agreement for study selection averaged 0.80. Relative association measures (relative risk, odds ratios, and hazard ratios [HRs]) and the associated 95% confidence intervals (CIs) were pooled across studies using a random-effects model. Heterogeneity in results across studies was assessed by the  $I^2$  statistic.

### A Systematic Review of Treatment of Intermittent Claudication in the Lower Extremities

#### Data Extraction and Analysis

Teams of reviewers working in duplicates reviewed abstracts and full-text articles and extracted descriptive, methodologic quality, and outcome data. Article review and data extraction were done using online systematic review software (DistillerSR, Ottawa, Ontario, Canada). Online electronic data extraction forms were piloted, then used. Chance-adjusted inter-reviewer agreement averaged 0.80.

Mixed treatment meta-analysis was planned but was later deemed not feasible because of the small number of trials included in each comparison in addition to the heterogeneity of trial populations. Descriptive narrative of the results is presented. Continuous variables were reported as mean, median, and standard-deviation, and categorical variables were reported as percentages.

## Methods Used to Formulate the Recommendations

### Expert Consensus

## Description of Methods Used to Formulate the Recommendations

The Society for Vascular Surgery (SVS) Lower Extremity Guidelines Committee began the process by developing a detailed outline of the diagnostic and management choices for peripheral arterial disease (PAD) by stage of disease. Given the broad scope of the field, the committee determined that this document should focus on the evaluation and management of asymptomatic disease and intermittent claudication (IC). Separate practice guidelines for critical limb ischemia (CLI) will be established in a future document. The committee developed sets of key questions and, with the input of a methodologist, condensed these into topics that framed systematic evidence reviews. The quantity and quality of evidence available was also an important factor in determining the rationale for the systematic review topics. De novo evidence reviews were undertaken to examine the rationale for screening in asymptomatic PAD and the comparative effectiveness of current treatments for IC. These systematic reviews are published jointly with this guideline document.

The committee developed the practice guideline by assigning two or three members to create primary drafts of each section of the document, highlighting specific questions where recommendations were needed and appropriate. Each section was then reviewed and revised by the remainder of the writing group and the two co-chairs. All guideline recommendations were reviewed by the full committee and finalized via an iterative, consensus process. In considering available treatment modalities, the committee focused on options currently available to patients and physicians in the United States (U.S.).



The Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework was used for determining the strength of recommendation and the quality of evidence, as previously reported. The quality of evidence is rated as high (A), moderate (B), or low (C). This rating is based on the risk of bias, precision, directness, consistency, and the size of the effect. The strength of recommendation is graded based on the quality of evidence, balance between benefits and harms, patients' values, preferences, and clinical context. Recommendations are graded as strong (1) or weak/conditional (2). The term "the Committee recommends" is used with strong recommendations, and the term "the Committee suggests" is used with conditional recommendations.

The methodologist assisted the committee in incorporating the evidence into the recommendations and helped in rating the quality of evidence and the strength of recommendations.

## Rating Scheme for the Strength of the Recommendations

### Grading of Recommendations Assessment, Development and Evaluation (GRADE) Recommendations Based on Level of Evidence

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Modified from Guyatt G, Gutterman D, Baumann MH, Addrizzo-Harris D, Hylek EM, Phillips B, et al. Grading strength of recommendations and quality of evidence in clinical guidelines: Report from an American College of Chest Physicians task force. *Chest* 2006;129:174-81.

## Cost Analysis

- The authors of "A systematic review for the screening for peripheral arterial disease in asymptomatic patients" (see the "Availability of Companion Documents" field) did not identify reliable studies of cost-effectiveness. Reliable cost-effectiveness and economic inferences require a trial comparing a screening strategy to no screening strategy, which was not available at the time of conducting the review.
- See "A systematic review of treatment of intermittent claudication in the lower extremities" for a discussion of cost-effectiveness information.

# Method of Guideline Validation

Internal Peer Review

## Description of Method of Guideline Validation

This guideline was reviewed by the Society for Vascular Surgery (SVS) Documents Oversight Committee that peer reviewed the document and provided content and methodology expertise.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

- Although antiplatelet therapy has not been conclusively proven to improve bypass graft patency, its benefit in decreasing long-term postprocedural adverse cardiovascular events is sufficient indication for the use of these agents in most patients, who are considered to be at high risk for cardiovascular complications and stroke.
- Given its efficacy as primary therapy, it is not surprising that a number of small trials have suggested the benefit of exercise as an adjunct to percutaneous or open interventions performed for treatment of intermittent claudication (IC).

### Potential Harms

- Some authors have raised caution about the failure mode of covered stents in femoropopliteal occlusive disease (FPOD), with a higher proportion of acute limb ischemia events compared with bare-metal stent (BMS), particularly when distal collateral vessels are covered.
- Pentoxifylline side effects of nausea, headache, drowsiness, and anorexia have precluded long-term use in some patients. Hypertension can be exacerbated with use.
- Performing prophylactic interventions in patients with intermittent claudication (IC) that is minimally symptomatic or well tolerated has no benefit, may cause harm, and is never indicated. Caution is warranted in the use of interventions for IC in anatomic settings where durability is limited (extensive calcification, small-caliber arteries, diffuse infrainguinal disease, poor runoff).
- Perioperative morbidity for surgical procedures may include cardiac, pulmonary, infectious, wound, and gastrointestinal complications. Long-term complications include limb occlusions, pseudoaneurysm, graft infection, and graft-enteric fistula. Caution should be exercised in the treatment of aortoiliac occlusive disease (AIOD) where concomitant aneurysm disease is also present.
- The efficacy of endovascular therapy (EVT) must also be weighed against the potential for acute and long-term complications. Common endovascular complications include arterial dissection at the area of treatment site, arterial perforation, pseudoaneurysm creation, acute recoil associated with abrupt closure or restenosis, embolization distal to the site of intervention, and arteriovenous fistula creation. Implantation of a stent also carries specific, stent-related risk factors, including stent fracture, chronic arterial erosion, and perforation. Long-term complications include restenosis with potential occlusion, loss of collateral branches at the site of the endovascular procedure, and late pseudoaneurysm formation. One additional consideration with EVT is its effect on subsequent open surgical bypass, which has been reported to be required in 10% to 25% of patients for failed interventions.
- Iliac stenting and direct surgical revascularization may have inferior outcomes in younger patients (<50 years).

## Contraindications

## Contraindications

- Cilostazol is contraindicated in patients with any level of heart failure.
- Angiotensin-converting enzyme inhibitors (ACEIs) are contraindicated in individuals with known renal artery stenosis.
- Many of the same factors that may render a patient a poor candidate for exercise therapy should be considered as relative contraindications to invasive treatments for intermittent claudication (IC) because they negatively affect the risk-to-benefit analysis.
- Gadolinium use for magnetic resonance angiography (MRA) is contraindicated in patients with significant renal impairment due to the potential risk of causing nephrogenic systemic fibrosis.
- MRA cannot be used in patients with pacemakers and a variety of other implanted medical devices.
- When performing surgical bypass for aortoiliac disease, concomitant aneurysmal disease of the aorta or iliac arteries should be treated as appropriate (exclusion) and is a contraindication to end-to-side proximal anastomoses.

## Qualifying Statements

### Qualifying Statements

In considering available treatment modalities, the committee focused on options currently available to patients and physicians in the United States (U.S.).

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.

### Implementation Tools

Mobile Device Resources

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Living with Illness

### IOM Domain

Effectiveness

Patient-centeredness

# Identifying Information and Availability

## Bibliographic Source(s)

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## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2015 Mar

## Guideline Developer(s)

Society for Vascular Surgery - Medical Specialty Society

## Source(s) of Funding

Society for Vascular Surgery

## Guideline Committee

Lower Extremity Guidelines Committee

## Composition of Group That Authored the Guideline

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## Financial Disclosures/Conflicts of Interest

All members of the committee provided updated disclosures on potential conflicts of interest (COI), in accordance with Society for Vascular Surgery (SVS) policies. The final roster of the Lower Extremity Guidelines Committee is in accordance with the current SVS COI policy, which is summarized elsewhere. COI disclosures for each of the writing group authors are listed at the end of the original guideline document in the Appendix.

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria

## Guideline Availability

Available from the [Journal of Vascular Surgery Web site](#) .

## Availability of Companion Documents

The following are available:

- Alahdab F, Wang AT, Elraiyah TA, Malgor RD, Rizvi AZ, Lane MA, Prokop LJ, Montori VM, Conte MS, Murad MH. A systematic review for the screening for peripheral arterial disease in asymptomatic patients. J Vasc Surg. 2015 Mar;61(3 Suppl):42S-53S. Available to subscribers from the [Journal of Vascular Surgery Web site](#) .
- Malgor RD, Alalahdab F, Elraiyah TA, Rizvi AZ, Lane MA, Prokop LJ, Phung OJ, Farah W, Montori VM, Conte MS, Murad MH. A systematic review of treatment of intermittent claudication in the lower extremities. J Vasc Surg. 2015 Mar;61(3 Suppl):54S-73S. Available to subscribers from the [Journal of Vascular Surgery Web site](#) .

A clinical practice guidelines app is available from the [Society for Vascular Surgery \(SVS\) Web site](#) .

## Patient Resources

The following is available:

- Patient resources. Vascular conditions: peripheral arterial disease (PAD). Available from the [Society for Vascular Surgery \(SVS\) Web site](#) .

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## NGC Status

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